

REMARKS/ARGUMENTS

Entry of the foregoing amendments and favorable reconsideration of the subject application, pursuant to and consistent with 37 C.F.R. Section 1.116, and in light of the remarks which follow, are respectfully requested. This amendment is in response to the final Office Action mailed on February 20, 2009. Claims 1 and 6 have been amended, claims 4, 5 and 7 are pending, and claim 8 is new. No new matter has been added by way of this amendment.

Foremost, the Examiner has rejected claims 1 and 4-7 under 35 U.S.C. 112, first paragraph, as allegedly failing to comply with the written description requirement. The Examiner contends that "[n]one of the water insoluble alkyl cellulose ether derivatives[,] water insoluble acrylic polymer derivatives and water insoluble vinyl derivatives[,] other than those examples provided on page 4 [of the specification,] meet the written description [requirement]." Office Action dated September 15, 2008, pages 2-3. Moreover, the Examiner contends that the "specification provides insufficient written description to support the genus of derivatives encompassed by the claim..." *Id.*

While Applicants disagree with the Examiner's contentions, and in an effort to expedite prosecution, Applicants have amended claims 1 and 6 to recite the specific water-insoluble macromolecular substances enumerated on page 4 of the pending application. In view of these amendments, the rejection should be withdrawn.

The Examiner has also rejected claim 6 under 35 U.S.C. §112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Office Action, page 6. In particular, the Examiner states that there

is insufficient antecedent basis for the limitation "said first and second layers." *Id.* To overcome this rejection, Applicants have amended claim 6 by replacing the language "said first and second layers" with "said first and second skin layers." Accordingly, this rejection should be withdrawn.

Claims 1 and 4-7 have been rejected under 35 U.S.C. 103(a) as being unpatentable over JP 02226416A, CAPLUS Abstract to *Hara et al.* (hereinafter "*Hara*") and further in view of U.S. Patent No. 5,068,112 to *Samejima et al.* (hereinafter "*Samejima*") and and U.S. Patent No. 5,405,617 to *Gowan Jr. et al.* (hereinafter "*Gowan*"). *Office Action*, pages 4-6. The Examiner further contends that it would have been obvious to combine the beraprost sodium granules of *Hara* with the granule sizes of *Samejima* and the taste mask coating of *Gowan* to arrive at the present invention. *Id.* Applicants respectfully disagree.

First, even if the references are combined they would not result in the claimed invention. *Hara* and *Samejima* both teach the addition of a single coating layer to a granule for the purpose of modifying the release properties of an active pharmaceutical ingredient ("API"). Neither of these references, however, disclose that two distinct coating layers are added to a granule as in the claimed invention.

Nor does *Gowa* cure this deficiency. *Gowa* is directed to the application of taste-masking agents to a formulation, either as a single layer coating or as part of a carrier matrix. Like *Hara* and *Samejima*, there is no disclosure or suggestion in *Gowa* that two different coating layers can be applied to a formulation. And certainly, there is no disclosure in *Gowa* that taste-masking layers can be used in conjunction with sustained or controlled release layers. Accordingly, there is no teaching in the collective references of a granule having two distinct coating layers as in the claimed invention.

Moreover, one skilled in the art would not have been

motivated by the teachings of Gowa to include a layer of an aliphatic or fatty acid ester in conjunction with another sustained release layer. As already mentioned, Gowa focuses on the use of aliphatic and fatty acid esters as taste-masking agents. Indeed, the entire disclosure of Gowa is directed to this purpose. For example, Gowa provides a detailed disclosure on the selection of appropriate taste-masking agents, the amount of such agent to include with an API to provide an acceptable taste-masking result, and methods of applying such an agent to an active pharmaceutical ingredient.

Missing from Gowa is any disclosure on the use of aliphatic or fatty acid esters as coating agents to provide improved bioavailability and sustained or controlled release of an API. In fact, Gowa teaches the opposite. Gowa specifically notes that "[a]liphatic or fatty acid esters themselves are poorly water soluble or insoluble in water and may inhibit ready release of the coated pharmaceutical actives." Col.4, ll.54-56. To overcome this, Gowa notes that water soluble additives could be added to increase the rate of API release when these coatings are included. *Id.* at 56-58. Certainly, one skilled in the art would not have been motivated to use these esters as sustained released coatings at least not with any reasonable probability of success. This is especially true in view of the express teachings of Gowa about the adverse effects of including such agents. Accordingly, the rejection should be withdrawn.

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejection of the claims and to pass this application to issue.

If, however, for any reason the Examiner does not believe that such action can be taken at this time, it is respectfully requested that he/she telephone applicant's

Application No.: 10/556,641

Docket No.: REGIM 3.3-069

attorney at (908) 654-5000 in order to overcome any additional objections which he might have.

If there are any additional charges in connection with this requested amendment, the Examiner is authorized to charge Deposit Account No. 12-1095 therefor.

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Respectfully submitted,

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